K123786

stryker

APR 0 9 2013

510(k) Summary

Date prepared:	December 6, 2012
Submitter:	Stryker Leibinger GmbH & Co. KG Bötzinger Straße 41 79111 Freiburg Germany
Contact:	Jamshed Badarpura Phone: (269) 389-4260 jamshed.badarpura@stryker.com Stryker Craniomaxillofacial 750 Trade Center Way Portage, MI 49002 USA
Proprietary Name:	Stryker Universal Orbital Floor System
Common Name:	Universal Orbital Floor
Proposed Regulatory Class:	Class II
Product Codes:	JEY – Bone Plate
Predicate Device:	Synthes Craniofacial Plate and Screw System - K080331

Intended Use:

The Stryker Universal Orbital Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit.

Indication for Use:

The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in adult patients.

Device Description:

The Stryker Universal Orbital Floor System comprises a pre-bent titanium orbital floor implant that approximates the shape and dimensions of the average normal orbital floor and medial wall (in order to facilitate the operative goal of restoring normal (pre-traumatic) orbital volume as accurately as possible), a globe retractor for retraction of

the orbital contents off the orbital floor and walls (in order to provide exposure of the fracture site(s)), and a plate-holding forceps (that facilitates the insertion and positioning of the plate within the orbit).

The plates are designed based on an average anatomical model of CT-scan data taken from 300 subjects (92% Caucasian). The metadata of the 300 subjects that have been included in the generation of the average anatomical model is listed in table 1. The selected scans were obtained from healthy subjects without any deformation of the bony orbital structures.

Table 1: Meta data of the 300 CT scans

Age [years]		Gender		Ethnic Group	
10-19	18	f	122	ca	276
20-29	19	m	178	me	3
30-39	20			xx	21
40-49	28				
50-59	36				
60-69	56				
70-79	72				
80-89	44				
90-99	6				

Age: 297 scans: age 15-95, 1 scan: age 14, 1 scan: 11, 1 scan: unknown; average age: 59 years;
Gender: 122 female (f) and 178 male (m);
Ethnic Group: 276 Caucasians (ca), 3 Middle-East (me), 21 unknown (xx)

The implant is provided in pre-bent left and right and in small and large sizes. A medial wall extension is attached to the floor section of the implant in order to provide coverage for a co-extensive medial wall fracture. If not needed, this medial wall extension may be removed by cutting through the designated cutting lines on the implant. The implant is fixed to the infra-orbital rim via either the holes on the provided fixation arms or through the anterior screw holes on the plate itself.

Clinical Testing:

No clinical testing was performed to support this submission.

Non-Clinical Testing:

The Stryker Universal Orbital Floor System was subjected to Verification and Validation testing of biocompatibility, cleaning, sterilization, corrosion resistance, stability of plate,

functionality over lifetime, transportation of the complete set and of packaging, an end product test and a design validation – end user test. The System passed all tests.

Comparison to Predicate Device

The Stryker Universal Orbital Floor System ("Subject Device") is compared to its Predicate Device for Substantial Equivalence. Side-by-side comparison tables summarizing the following criteria are provided below:

A: Intended Use
B: Principle of Operation
C: Technological Characteristics
D: Packaging

A: Indications for Use

Table 1: Substantial Equivalence of Indications for Use

	Subject Device	Predicate Device
Intended Use	Intended Use: The Stryker Universal Orbital Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit. Indications for Use: The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in adult patients.	Intended Use / Indications for Use: The Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the midface and craniofacial skeleton, craniofacial surgery, reconstructive procedures and selective orthognathic surgery of the maxilla and chin. Indications Synthes MatrixMIDFACE Preformed Orbital Plates are intended for trauma repair and reconstruction of the craniofacial skeleton. – Orbital floor fractures – Medial orbital wall fractures – Combined orbital floor and medial wall fractures

The intended use of the Subject Device is included in the intended use of the Predicate Device. The Predicate has the same indications for use as the Subject Device, though without age specification.

B: Principle of Operation

Table 2: Substantial Equivalence of Principle of Operation

	Subject Device	Predicate Device
Application Area	CMF/Orbital	CMF/Orbital
Operational principle	Reconstruct the orbital floor and/or medial wall	Reconstruct the orbital floor and/or medial wall
Mode of fixation	Plate fixation with screws inserted through dedicated screw holes.	Plate fixation with screws inserted through dedicated screw holes.
Duration of implantation within the body	Permanent implant	Permanent implant

The basic operational principle of the Subject Device, as well as the Predicate Device, is to reconstruct the orbital floor and/or medial wall. The fixation method of both the Subject Device and the Predicate is with screws inserted through dedicated screw holes. The Subject Device and the Predicate Device are both permanent implants.

C: Technological Characteristics

Table 3: Substantial Equivalence of Technological Characteristics

	Subject Device	Predicate Device
Material	Commercially Pure Titanium	Pure Titanium
Design	3D pre-bent plate based on average anatomical model; 0.4mm thickness; Based on average anatomical model of 300 CT-scans and comprising 276 Caucasian subjects (92%)	3D pre-bent plate based on average anatomical model; 0.4mm thickness Based on average anatomical model of 279 Caucasian CT-scans
Mode of Modification	Cutting / trimming along dedicated lines; pliable mesh structure for bending	Cutting / trimming along dedicated lines; pliable mesh structure for bending
Sizes	2 sizes: large and small for left and right each	2 sizes: large and small for left and right each
Dimensions	Large Plate: L=35mm, W=36mm, H=16mm Small Plate: L=31mm W=34mm, H=12mm	Large Plate: L=35mm, W=38mm, H=18mm Small Plate: L=35mm, W=34mm, H=10mm
Screw Holes	• For 1.2 mm, 1.4 mm and 1.7 mm screws • Number of screw holes along rim: 4 • Two screw fixation arms with a number of 2 screw holes each • Position of screw fixation arms at 1st and 3rd screw hole from medial	• For 1.5 mm and 1.8 mm screws • Number of screw holes along rim: 4 • Two screw fixation arms with a number of 2 screw holes each • Position of screw fixation arms at 1st and 2nd screw hole from medial

The Subject Device is made of biocompatible commercially pure titanium (CP Ti Grade 2); the Predicate is made of pure titanium.
The Subject Device is pre-bent in a 3D shape and size similar to the Predicate Device.

D: Packaging

Table 4: Technological Characteristics of Packaging

	Subject Device	Predicate Device
Packaging	Non-sterile	Non-sterile / sterile

The Subject Device is delivered non-sterile. The Predicate Device is delivered non-sterile and sterile.

Substantial Equivalence Conclusion:

The Stryker Universal Orbital Floor System has similar material and technological characteristics, and the same principal of operation as the Predicate Device. The intended use and indications for use are nearly identical to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2013

Mr. Jamshed Badarpura
Regulatory Compliance Analyst
Stryker
750 Trade Center Way
PORTAGE MI 49002

Re: K123786
Trade/Device Name: Stryker Universal Orbital Floor System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 4, 2013
Received: March 7, 2013

Dear Mr. Badarpura:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S FDA for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123786

Device Name: Stryker Universal Orbital Floor System

Indications For Use: The Stryker Universal Orbital Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit.

The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in adult patients.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.04.05
12:24:33 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123786